4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2011-N-0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Hydrocortisone Aceponate, Miconazole Nitrate, and Gentamicin Sulfate Otic Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Virbac AH, Inc. The NADA provides for the veterinary prescription use of a hydrocortisone aceponate, miconazole nitrate, and gentamicin sulfate suspension for the treatment of otitis externa in dogs.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Fort Worth, TX 76137, filed NADA 141-330 for the veterinary prescription use of EASOTIC (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Suspension for the treatment of otitis externa in dogs associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius). The NADA is approved as of October 31, 2011, and 21 CFR part 524 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority

delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Add § 524.1132 to read as follows:

§ 524.1132 Hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate otic suspension.

(a) Specifications. Each milliliter (mL) of suspension contains 1.11 milligrams (mg) of hydrocortisone aceponate, 15.1 mg of miconazole nitrate, and 1,505 micrograms of gentamicin sulfate.

(b) Sponsor. See No.051311 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Instill 1.0 mL in the affected ear once daily for 5 days.

(2) Indications for use. For the treatment of otitis externa in dogs associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius).

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 13, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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